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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,473	10/09/2001	Nahum Sonenberg	514012000400	5331

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/20/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,473

Applicant(s)

SONENBERG ET AL.

Examiner

Deborah J. Reynolds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a transgenic animal, cells isolated therefrom, and a method of making the animal, classified in class 800, subclass 13, for instance.
- II. Claims 7-20, drawn to a method of identifying an agent which modulates glucose or fat metabolism in vivo comprising measuring glucose and/or lipid levels, classified in class 424, subclass 9.2, for instance.
- III. Claims 21 and 38, drawn to a modulator of glucose or fat metabolism identified by the method of group II, unclassifiable because the compound is not defined.
- IV. Claims 22-25, 32-33, 39-40, drawn to a method of decreasing fat tissue growth or weight gain by administering an antibody, classified in class 424, subclass 130.1, for instance.
- V. Claims 22, 23, 24-26, 32-33, 39-40, drawn to a method of decreasing fat tissue growth or weight gain by administering an antisense RNA, classified in class 514, subclass 44.
- VI. Claims 27-30, drawn to a method of determining whether an agent modulates fat tissue growth and/or weight gain in an animal comprising

measuring fat tissue growth and/or weight gain, classified in class 424, subclass 9.2, for instance.

- VII. Claims 31 and 38, drawn to a modulator of glucose or fat metabolism identified by the method of group VI, unclassifiable because the composition is undefined.
- VIII. Claims 34-37, drawn to a method of determining whether an agent modulates obesity in an animal comprising assessing obesity, classified in class 424, subclass 9.2.
- IX. Claim 38, drawn to a modulator of glucose and/or fat metabolism identified by the method of group VIII, unclassifiable because the composition is undefined.
- X. Claim 41, drawn to a method of identifying an agent which modulates glucose and/or fat metabolism in vivo comprising assessing binding of a portion of eIF-4E and a peptide in the presence or absence of the agent, classified in class 424, subclass 9.2.

Claims 22, 23, 25, 32, 33, 39, and 40 link(s) inventions IV and V. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are

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presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, IV, V, VI, VIII, or X are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the animal of group I could be used in the methods of the groups listed, however, none of the groups specifically require use of the animal of group I. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I and III, VII, or IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Moreover, the animal of group I is not

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disclosed as being used with the compositions of groups III, VII, or IX. The animal is entirely patentably distinct from the claimed compositions. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II, VI, VIII, and X are directed to patentably distinct methods.

Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods that each have different modes of operation. In particular the different methods require *in vivo* testing but they each require measurement of a distinct parameter. For example, the method of Group II requires measuring glucose or lipid levels, the method of Group VI requires measuring fat tissue growth or weight gain, the method of Group VIII requires assessing obesity, and the method of Group X assessing binding of a portion of eIF-4E and a peptide. As such it is clear that methods embraced by each of the Groups requires different technical considerations and chemically different reagents for practice. Therefore, the inventions are practiced in a wholly distinct manner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II, IV, V, VI, VIII, or X and III, VII, or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in a materially different process of using the product. Moreover, the claims are not limited to any particular type of modulator. However, if the modulator is a nucleic acid molecule, such may be used in a hybridization assay *in vitro*; if the modulator is a protein, such may be used as an antigen to generate antibodies in an animal; if the modulator is an antibody, such may be used to identify an antigen in an immunofluorescence assay in a somatic cell *in vitro*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions III, VII, and IX are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different classes of undisclosed modulators having different functions, which may be identified by distinct methods. Since the modulators are unidentified they may comprise widely varying chemical structures and may be used in distinct methods that require

different technical considerations. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II, VI, VIII, or X and IV or V are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct methods that have different modes of operation and different effects. For example, the methods of Groups II, VI, VIII, and X are screening methods for identifying candidate agents that modulate different aspects of glucose or fat metabolism while the methods of Groups IV and V appear to be therapeutic in nature as they are directed to methods of decreasing fat tissue growth or weight gain. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions IV and V are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to similar methods having different modes of operation, as they require chemically different products for practice. For example the method of Group IV requires use of antibody to

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decrease weight gain while the method of Group V requires use of antisense RNA to decrease weight gain. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and require a different search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication should be directed to Deborah J. Reynolds at telephone number 703-305-4051.


Deborah J. Reynolds
SPE
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